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07/346,165 05/02/89 FERRARA

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QUESTIONS

186

7

02/01/90

☐ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892.        | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.             | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____  |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-40 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2. ☐ Claims \_\_\_\_\_ have been cancelled.

3. ☐ Claims \_\_\_\_\_ are allowed.

4. ☐ Claims \_\_\_\_\_ are rejected.

5. ☐ Claims \_\_\_\_\_ are objected to.

6. ☒ Claims 1-40 are subject to restriction or election requirement.

7. ☒ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

Serial number: 346165

Art unit: 186

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 12-25, 33-36, and 38-40, drawn to a growth factor, an in vitro method of using, and methods of producing, classified in Class 530, subclasses 397 and 399.

II. Claims 6-11, 30-32, and 37, drawn to in vivo methods of using and a pharmaceutical composition, classified in Class 530, subclasses 397 and 399; and Class 514, subclasses 8, 12, and 21.

III. Claims 26-29, drawn to a process of producing the growth factor, classified in Class 530, subclass 397.

Inventions I and II are related as product (the growth factor) and process of use (in vivo methods of using). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as for in vitro use in cell culture media.

Inventions I and II are related as mutually exclusive species in intermediate-final (growth factor-pharmaceutical composition) product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful other than to make the final product (MPEP section 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP section 806.04(h)).

In the instant case, the intermediate product is deemed to be useful as a growth factor for use in compositions such as cell culture media and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Inventions III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2)

that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as by automated synthesis.

A telephone call was made to Howard Peters on January 26, 1990 to request an oral election to the above restriction requirement, but did not result in an election being made.

In the preliminary examination of the claims, there appear to be duplicate claims. Claim 21 appears to be the same as claim 1, and Claim 36 appears to be the same as claim 15. In order to expedite examination, it would be beneficial for the applicant to clarify the apparent discrepancies in these claims in the response to the above restriction requirement.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

*MS*  
SJS

January 30, 1990

*M. Moskowitz*  
MARGARET MOSKOWITZ  
SUPERVISORY  
PATENT EXAMINER  
ART UNIT 186